K120662

APR 2 4 2012

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ABAXIS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

1. Applicant Information:

Date Prepared:	March 2, 2012
Name:	Abaxis, Inc.
Address:	3240 Whipple Road Union City, CA 94587
Contact Person:	Dennis M. Bleile, PhD
Phone Number:	(510) 675-6515
Fax Number:	(510) 405-8871

2. Device Information:

Classification	Class I
Trade Name:	Piccolo® HDL - Capillary Test System
Classification Name:	HDL Test system 862.1475

3. Identification of Legally Marketed Device to which the Submitter Claims Equivalence:

The following table identifies the legally marketed devices to which Abaxis claims equivalence:

Predicate Device			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
Piccolo® HDL Test System	Abaxis	K023640	1/24/2003
Cobas® HDL-Cholesterol Plus 3rd Generation	Roche Diagnostics Indianapolis, IN	K033610	12/05/2003

Summary of Safety and Effectiveness (continued)

4. Description of the Device:

The Piccolo® Lipid Panel – Capillary Reagent Disc (which contains the Piccolo® HDL – Capillary Test System) is designed to separate a heparinized whole blood sample into plasma and blood cells. The disc meters the required quantity of plasma and diluent, mixes the plasma with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted plasma mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer.

5. Statement of Intended Use:

The Piccolo HDL – Capillary Test System used with the Piccolo xpress Chemistry Analyzer is intended for the *in vitro* quantitative determination of HDL in capillary (fingerstick) heparinized whole blood in a clinical laboratory setting or point-of-care location.

6. Summary of the Technological Characteristics of the New Device in Comparison to those of the Predicate Device:

Table 1 outlines the technological characteristics of the Piccolo® HDL – Capillary Test System in comparison to the legally marketed predicate device.

Summary of Safety and Effectiveness (continued)

Table 1: Specification Comparison for Piccolo HDL – Capillary Test System, Piccolo HDL Test System, and the Roche HDL Test on the Cobas 6000 Analyzer

	Piccolo HDL – Capillary Test System on Abaxis Chemistry Analyzer	Piccolo HDL Test System on Abaxis Chemistry Analyzer	Roche Diagnostics Cobas® HDL-Cholesterol Plus 3rd Generation Test
Intended Use	Quantitative analysis of HDL	Quantitative analysis of HDL	Quantitative analysis of HDL
Methodology	Hybrid enzymatic colorimetric end-point test, making use of dextran/sulfate precipitation, centrifugation, and PEG-modified enzymes	Hybrid enzymatic colorimetric end-point test, making use of dextran/sulfate precipitation, centrifugation, and PEG-modified enzymes	Homogeneous enzymatic colorimetric end-point test, making use of dextran/sulfate suspension and PEG-modified enzymes
Sample Type	Lithium heparinized capillary whole blood	Lithium heparinized whole blood, heparinized plasma, and serum	Lithium heparin and potassium EDTA plasma and serum
Dynamic Range Lower Limit	15 mg/dL	15 mg/dL	3 mg/dL
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Liquid reagents
Temperature of Reaction	37°C	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
Assay Range	15 – 100 mg/dL	15 – 100 mg/dL	3 - 120 mg/dL
Testing Environment	Professional use	Professional use	Professional use

Summary of Safety and Effectiveness (continued)

7. Brief Discussion of the Clinical and Nonclinical Tests Relied on for a Determination of Substantial Equivalence.

The following information summarizes the results of clinical and non-clinical tests performed using the Piccolo® HDL Test System.

Linearity:

Table 2: Summary of Linearity

	HDL
Slope	0.983
Intercept	0.5
Correlation Coefficient (r)	0.997

Precision:

Precision studies were designed to evaluate within-run and total precision of HDL included on the Piccolo® Lipid Panel Reagent Disc when run on the Piccolo® Point-of-Care Chemistry Analyzer.

Table 3: Within-Run and Total Precision of HDL Assayed on the Piccolo® Point-of-Care Chemistry Analyzer

	Within-Run (n =160)	Total (n =160)
HDL (mg/dL)		
Serum 1		
Mean	55.3	55.3
SD	1.4	1.9
%CV	2.6	3.5
Serum 2		
Mean	38.0	38.0
SD	1.3	1.6
%CV	3.5	4.3

Summary of Safety and Effectiveness (continued)

Method Comparison:

Table 4: Method Comparison Data for HDL Assayed by the Abaxis Piccolo HDL – Capillary Test System and the Roche HDL Test

Parameters	Statistics
Piccolo HDL – Capillary: Singlicate Values, N	559
Roche HDL Test: Average of Duplicates, N	559
Piccolo HDL – Capillary: Mean	47.2
Roche HDL Test: Mean	49.3
Piccolo HDL – Capillary: Std. Dev.	13.9
Roche HDL Test: Std. Dev	13.8
Piccolo HDL – Capillary: Range of Samples	21 - 93
Roche HDL Test: Range of Samples	23 – 92.5

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	559	559
Slope (95% CI)	0.99 (0.97 to 1.01)	1.01 (0.99 to 1.03)
Intercept	-1.6 (-2.4 to -0.8)	-2.6 (-3.4 to -1.7)
Correlation Coefficient (R^2)	0.962	0.962
Std. Error of the Estimate (SEE)	2.7	2.7

8. Conclusions

The clinical and non-clinical tests performed using the Piccolo® HDL – Capillary Test System, when run on the Piccolo® xpress Chemistry Analyzer, demonstrate that the test system is as safe, effective and performs as well as the legally marketed devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Abaxis Inc.
c/o Dennis Bleile, Ph.D.
3240 Whipple Road
Union City, CA 94587

APR 2 4 2012

Re: k120662

Trade/Device Name: Piccolo® HDL Capillary Test System
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(9)
Product Code: JHM
Dated: March 2, 2012
Received: March 5, 2012

Dear Dr. Bleile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

12.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): k120662

Device Name: **Piccolo® HDL - Capillary Test System**

Indications for Use:

The Piccolo HDL – Capillary Test System used with the Piccolo xpress Chemistry Analyzer is intended for the *in vitro* quantitative determination of HDL in capillary (fingerstick) heparinized whole blood in a clinical laboratory setting or point-of-care location.

Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Prescription Use ___X___ (Part 21 CFR 801.109 Subpart D) AND/OR Over- The Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k120662

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(Optional Format 1-2-96)